

REMARKS

Claims 1, 2 and 5-11 have been examined and stand rejected. The previous rejection of claims 1, 2, 5, 6 and 9-11 over an Australian provisional application and two additional references has been withdrawn "in view of the newly discovered prior art." Applicant maintains that this previous rejection is improper because the Australian document is not prior art to this application, regardless of the presence or absence of any additional art references.

Claims 1-2, 5-6 and 9-11 are rejected as anticipated by Zaia et al., Hematology, pp. 339-355, a reference cited by Applicant March 8, 2004 (hereinafter "Zaia"). In particular, the Office Action refers to disclosure in Zaia at page 351, second column and page 352, Table 2. Page 351, second column and page 352 are a list of references and do not contain such disclosure or a Table 2. Applicant assumes that pages 350-351 were intended. Applicant has amended the independent claims to recite the feature that the vaccine and the fusion peptide are unlipidated. Support for this amendment is found throughout the specification, which describes an unlipidated vaccine, and particularly at paragraph 24, which specifically states that the peptides are unlipidated and that the vaccines are effective without lipid modification.

The Zaia reference discloses fusion peptides and vaccines which are lipidated (see page 350, left column, line 10; page 350, right column, line 45; page 351, left column, first full paragraph, and Table 2) or which require harsh inflammatory adjuvants such as Freund's incomplete adjuvant (which is unsuitable for use in humans) in order to be effective. No effective unlipidated vaccine fusion peptides are disclosed or even hinted at in the Zaia reference. The conventional wisdom at the time this application was filed, and when the Zaia reference was published, was that peptide vaccines of this type would not function unless lipidated or administered with an inflammatory adjuvant such as Freund's (IFA) or alum, for example. The teachings of Zaia reflect this belief since the peptides were administered in lipidated form by Zaia. The authors of Zaia

also note that the even lipidated peptides are not functional as immunogenic vaccines if the lipid chains are shorter than 16 carbons. Thus, the teachings of Zaia, when taken as a whole, teach the skilled person that lipids are required for these types of peptide vaccines.

The present invention, however, relates to unlipidated fusion peptide vaccines which surprisingly are effective even without the lipids previously thought to be necessary. Applicant is submitting herewith a Declaration under 37 C.F.R. § 1.132, executed by Dr. Don Diamond, the inventor of the present invention. In this Declaration, Dr. Diamond explains that prior to the filing date of this application, skilled persons in this field considered covalently attached long lipid chains to be required for activity. The art available prior to this invention, including the Zaia reference cited here, taught that peptide epitope vaccines could result in a CTL response when lipidated. The art generally, and Zaia in particular, did not teach, or even suggest, that unlipidated fusion peptides would be effective or could be used.

Applicant therefore submits that Zaia does not teach all elements of the claims presented here and cannot anticipate these claims. Applicant therefore requests withdrawal of the rejection on grounds of anticipation of Zaia.

Claims 1-2 and 5-11 are rejected as obvious over the Zaia reference in view of Krieg et al., "WO122972 30 Apr 2001" [sic]. The Krieg reference was mentioned in a previous Office Action, but does not appear to have been formally cited against this application or to be formally of record in this case. Applicant assumes that the reference intended to be cited is Krieg et al., WO 01/22972, bearing a publication date of April 5, 2001 (hereinafter "Krieg"). Applicant requests that all references cited against the application in an Office Action be formally and correctly cited to maintain a clear record.

Zaia is cited for the disclosures discussed above with respect to the anticipation rejection concerning fusion peptides. As discussed above, Zaia completely fails to teach any unlipidated peptide vaccine as claimed here, and in fact, suggests that

unlipidated peptides such as claimed here would be inactive by remarking that peptides containing lipids shorter than 16 carbon atoms in length were inactive. This strongly suggests that long lipid chains are required for activity and teaches away from the present invention.


The Diamond Declaration accompanying this response explains that the knowledge in the art at the time this application was filed and the teachings of Zaia as a whole, disclosed to the skilled person that unlipidated peptides did not function. The art, therefore, does not suggest that the lipids of Zaia should be removed and does not provide any guidance to do so or any reasonable expectation of success if it were done.

Krieg is cited for disclosure of immunostimulatory nucleic acids. This reference relates to T-rich immunostimulatory nucleic acids of a different kind, but discuss bacterial-type CpG motifs by way of background and generally as immune stimulants. Krieg does not discuss the use of CpG DNA with fusion peptide vaccines as claimed here. Krieg does not suggest that the invention claimed here should be attempted or would succeed. Therefore, Krieg does not make up for the deficiencies of Zaia as discussed. Even in combination, the Zaia and Krieg references do not teach or suggest a fusion peptide without lipidation, do not guide the reader to modify Zaia by omitting lipidation and do not provide a reasonable expectation that the claimed fusion peptide would be effective as shown in the present application, either alone or with CpG DNA adjuvant.

In summary, Zaia does not teach or provide any guidance concerning unlipidated fusion peptide vaccines and Krieg does not make up for this complete lack of guidance. The references therefore cannot render the invention claimed here obvious. Applicant requests that the rejection be withdrawn.

Applicant requests reconsideration of the application at this time and allowance of the claims as amended.

The Office is authorized to charge any fees deemed necessary in connection with this filing to Deposit Account 02-2135.

Respectfully Submitted,					
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